IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	
Guerin-Marchand	Group Art Unit: 1648
Application No.: 09/900,963	Examiner: Shanon A. Foley
Filed: July 10, 2001	Confirmation No.: 8667
For: Peptide Sequences Specific for the Hepatic Stages of P. Falciparum Bearing Epitopes Capable of Stimulating the T Lymphocytes	

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In complete response to the Official Action dated June 14, 2001, requiring restriction under 35 U.S.C. §121, Applicants hereby elect, albeit with traverse, the claims of Group I, Claims 27, 28, and 35, drawn to a DNA sequence encoding a polypeptide consisting of the amino acid sequence of Figure 9. In the event that Applicants' traversal of this Restriction Requirement is not found persuasive, Applicants reserve the right to file divisional application(s) pertaining to any canceled subject matter.

First, Applicants respectfully direct the Examiner's attention to MPEP 803.04, which relates to restriction of claims to nucleotide sequences. This section states that

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 *et seq.* Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the restriction requirements of 37 CFR 1.141(a) *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application. * * *

> It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

Manual of Patent Examining Procedure, at 800-10. In view of this clear statement from the Commissioner, Applicants respectfully request that the present Restriction Requirement be modified to the extent necessary so that ten independent and distinct nucleotide sequences may be examined in this application.

Groups I and II

The Examiner has divided the claims in this application into ten groups. The first seven all relate to DNA sequences. Group I, as set forth by the Examiner, includes "claims 27, 28, and 35, drawn to a DNA sequence encoding a polypeptide consisting of the amino acid sequence of Figure 9." Group II, as set forth by the Examiner, includes "claims 27, 28, and 35, drawn to a DNA sequence encoding a polypeptide consisting of the amino acid sequence of Figure 10." However, figures 9 and 10 are the same, in that they represent the same sequence, which is an incomplete sequence of LSA-1 (3' part of the complete gene). Although the caption of Figure 9 indicates that it contains 1496 nucleotides, in fact the figure only includes 1494 nucleotides. Compared to the complete sequence disclosed in GenBank (Access number Z30320, attached hereto as Exhibit A), the sequence shown in Figure 9 lacks two T nucleotides at its 3' end. Although the caption of Figure 10 indicates that it contains 1482 base pairs, in fact, Figure 10 shows the same 1494 nucleotides sequence as Figure 9. Moreover, the last four amino acids (lys-val-ile-tyr) shown in these figures appear after the TAA stop codon, and so the nucleotides that correspond to these amino acids are

not included within the claimed sequence.[1] Since Figures 9 and 10 show sequences that encode the same protein, the inventions classified Group I and Group II by the Examiner cannot be considered to be independent and distinct inventions. Rejoinder of Groups I and II is thus respectfully requested.

Groups III-VII

Groups III-VII, as set forth by the Examiner, are directed to DNA sequences encoding polypeptides consisting of the amino acid sequence of SEQ ID NO: 19 (Group III); SEQ ID NO: 20 (Group IV); SEQ ID NO: 21 (Group V); SEQ ID NO: 22 (Group VI);and SEQ ID NO: 23 (Group VII). However, the amino acids sequences of SEQ ID NOs: 19, 20, 21, 22 and 23 are sub-sequences of the same protein. In view of the discussion of MPEP 803.04 above, Applicants respectfully submit that rejoinder of Groups III-VII is appropriate, and is respectfully requested.

The Examiner has also requested that if "applicant elects any of inventions III-VII, applicant must also elect an amino acid sequence that precedes the elected DNA sequence encoding the polypeptide selected from SEQ ID NOs: 2-18, recited in claim 30." In this context, the Examiner's attention is respectfully directed to subsection of MPEP 803.04 bearing the heading "Examples of Nucleotide Sequence Claims," which states in pertinent part,

> Examples of typical nucleotide sequence claims impacted by the partial waiver of 37 CFR 1.141 *et seq.* (and the partial waiver of 37 CFR 1.475 and 1.499 *et seq.*, see MPEP § 1850) include:
>
> * * *
>
> (B) a combination of DNA fragments comprising SEQ ID Nos. 1-1000;
>
> * * *
>
> Applications claiming only a combination of nucleotide sequences, such as set forth in example (B), will generally not be subject to restriction requirement. The presence of one novel and nonobvious sequence within

[1] This may be seen in Figure 8, which represents the same nucleotide sequence.

> the combination will render the entire combination allowable. The combination will be searched until one nucleotide sequence is found to be allowable. The order of searching will be chosen by the examiner to maximize the identification of an allowable sequence.

Manual of Patent Examining Procedure at p. 800-10. Applying this reasoning to the present case, a DNA sequence according to claim 30 is patentable if the corresponding DNA according to claim 29 (*i.e.,* a DNA of SEQ ID No: 19, 20, 21, 22 or 23) is patentable. Consequently, Applicants respectfully submit that the requirement for election of amino acid species is not sustainable, and should be withdrawn.

In view of the discussion above, Applicants believe that at least the following six sequences can properly be searched in the present application:

1. Nucleotides 1-1494 of the sequences of Figures 9 and 10 (Groups I & II);
2. SEQ ID NO: 19 (Group III, corresponding to amino acid positions 214-230);
3. SEQ ID NO: 20 (Group IV, corresponding to amino acid positions 203-320);
4. SEQ ID NO: 21 (Group V, corresponding to amino acid positions 217-243);
5. SEQ ID NO: 22 (Group VI, corresponding to amino acid positions 197-220); and
6. SEQ ID NO: 23 (Group VII, corresponding to amino acid positions 270-300).

Groups VIII and IX

Groups VIII and IX, as set forth by the Examiner are directed to DNA sequences encoding a polypeptide consisting of the amino acid sequence of Fig. 7 (Group VIII) and a DNA sequence encoding a polypeptide consisting of the first 153 amino acids of SEQ ID NO: 37. (Group IX). However, the sequences shown in Figure 7 are those of SEQ ID No: 37. They correspond to the 5' part of the LSA-1 gene (nucleotides 33-986 of the sequence at Genbank access number Z30319, attached hereto as Exhibit B). Thus, these two groups do not represent patentably distinct inventions, as discussed in MPEP 803.04. Rejoinder of Groups VIII and IX is thus respectfully requested. In view of the discussion above, and

taking into account the fact that degenerate sequences can be searched easily, Applicants respectfully request that the following expressly disclosed sequences be added to the list of those to be examined in the present application:

7. The nucleotide sequence of SEQ ID NO: 37; and
8. The nucleotide sequence encoding amino acids 1-153 of SEQ ID NO: 37 (nucleotides 1-458).

At page 4 of the Official Action, the Examiner requests that if "applicant elects invention IX, applicant must also elect one amino acid sequence that precedes and one amino acid sequence that follows the elected DNA sequence encoding the polypeptide selected from SEQ ID NOs: 2-18, recited in claims 33 and 34, respectively." Applicants respectfully reiterate their comments set forth above pertaining to the Examiner's similar requirement in connection with claim 30. Applicants respectfully submit that the requirement for election of amino acid species with regard to Group IX is likewise not sustainable, and should be withdrawn.

Group X

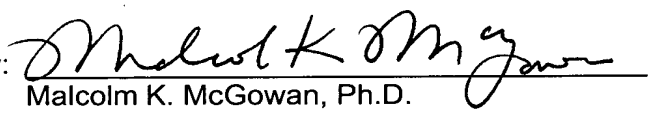
As described by the Examiner at page 4 of the Official Action, Group X is directed to "a DNA sequence encoding a polypeptide consisting of the last 279 amino acids of SEQ ID NO: 45." However, the nucleotide sequences of SEQ ID Nos: 41 and 45 are identical and are the same as those of Figures 9 and 10. Therefore, Applicants respectfully request rejoinder of Group X with Groups I and II. Applicants respectfully suggest that a search for these Groups could be performed based on the first 837 nucleotides of SEQ ID No: 45, encoding amino acids 1-279.

Conclusion

In view of the foregoing, withdrawal of the restriction requirement, and further and favorable consideration of all the claims of record on the merits is respectfully requested. In the event that there are any questions relating to this application, the Examiner is respectfully requested to telephone the undersigned so that prosecution of this application may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: 
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